

King, Valerie A.

From: Aimee Devor [adevor@clinimetrics.com]
Sent: Friday, April 25, 2003 9:58 AM
To: Mohamadi.Sarkar@pmusa.com
Cc: Valerie.A.King@pmusa.com; 'Bernie Linner'
Subject: SCoR2003-6/02/02

Dear Mohamadi,

Susanna Berelovich and Kathy Kundla have been working very diligently over the last two months at MDS in Lincoln to monitor the SCoR2003-6/02/02 protocol to meet the timeline MDS established of having all data monitored in April. They have run into a number of problems throughout the trial as noted in previous visit reports. Although very good, the data has been very slow to be entered into the database. The original request to have data monitored by April 1 was not met because MDS did not have data entered and ready for review. MDS moved the timeline to today, April 25th to have all data monitored. Susanna contacted Megan last Friday to ensure that all data would be available and ready for review when they arrived in Lincoln on Tuesday, April 22nd but received no return call. Susanna learned when she and Kathy arrived at MDS that they had not yet entered all data. MDS has provided the data this week to the CRAs for review in small increments making the time spent reviewing data less efficient and extended periods of downtime while the CRAs wait for the next batch of data.

This "piece meal" process of providing the data has been prevalent throughout this study and has affected our overall ability to monitor the data in the most efficient matter. This week's delay in having data available for monitoring has resulted in another missed deadline and necessitates a return visit to Lincoln the week of May 5th to complete the monitoring. Kim has confirmed that all data is now entered and will be available for review the week of May 5th. Clinimetrics will be sending three CRAs to Lincoln to ensure all review is completed within that week. Please also note that these additional visits may very likely result in additional costs to Philip Morris beyond the scope of the work initially agreed upon. I have relayed my concerns to Bernie Linner who will be in contact with Valerie to further discuss the monetary impact this may have.

If you have any concerns, please feel free to contact me via email or phone at 614.659.0561.

Kind regards,
Aimee